Patient generated data

Patients would generate different data all along the medicines' life-cycle

François Houÿez

Real-time feedback – COVID-19, France

Renaloo, social network of patients with kidney transplant or dialysis

- 22 June to 12 July 2020: 2,030 respondents / 10,000 members
  - Only 33% had a direct contact with nephrologist during the 2-month lockdown
  - 25% of those on renal transplant waiting list: not informed of the suspension of adult kidney transplantation
- 4 to 23 February 2021: 2,300 respondents
  - 96% were or wished to be vaccinated (versus 64% in general population at that time)
- July 2021: 2,389 respondents
  - 85.4% dialysed and 87.8% transplanted got at least one vaccine dose
- October 2021
  - 2 months after Ronapreve® CU started, despite "DGS urgent" only 2% of 57,000 patients (CU indication) were treated
- March 2022
  - > 75% of kidney transplant patients inadequately protected by vaccination still not received Evusheld® prophylaxis (CU opened December 2021)

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RARE DISEASES EUROPE

These are our needs.
Which technology can help?
How to measure effect?

Methods	Surveys, Mixed methods, PRelevantOs, GAS…
Patient Engagement	Community Advisory Boards (CABs) NEEDs project

Here's a candidate technology. How to develop it?

HTA

Methods	Qualitative
Patient Engagement	Scientific Advice

Patients generate data

GO or NOGO

Methods	PPE Study
Patient Engagement	CABs

Healthcare RWD

Methods	Own data entry, Connected devices, registries
Patient Engagement	Governance in data sources

Decision-making

HTA

Methods	Qualitative: expectations, what matters Best Worst Scaling: ranking, priorities DCE: to which extent? PPE Spontaneous reporting susp. ADRs
Patient Engagement	CHMP Early contribution, (Effects Table) SAG, consultations (B/R, pharmacovigilance…) HTA and appraisal

Call to Action!

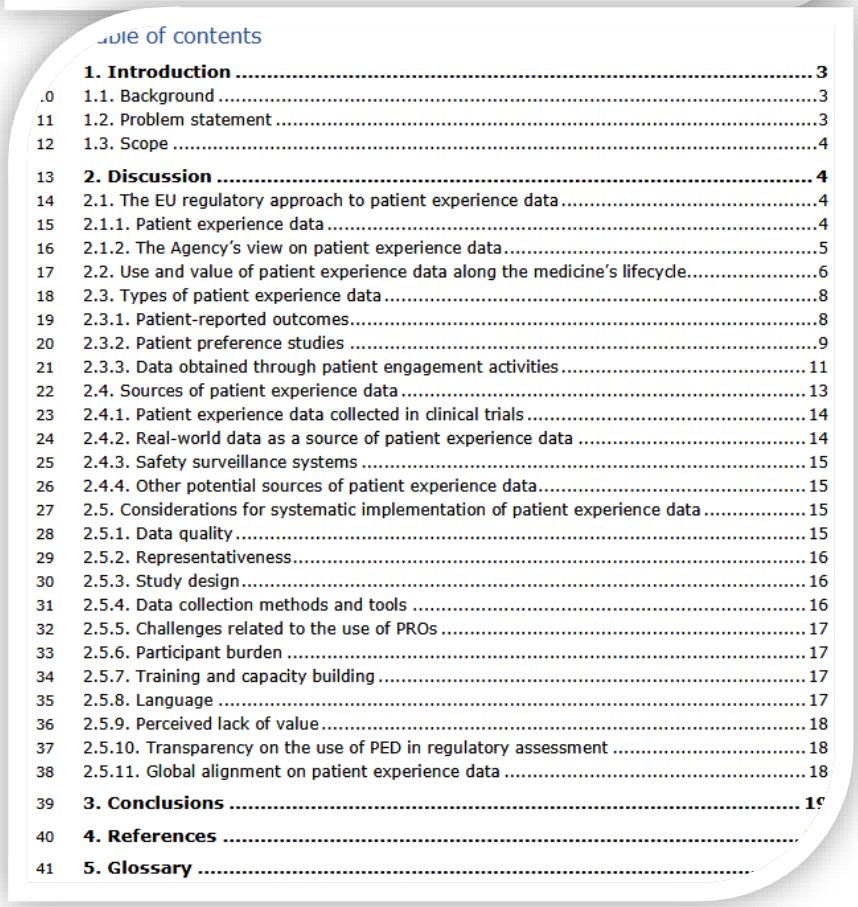
Express your views on the Reflection Paper on Patient Experience Data

Consultation until 31 January 2026

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 September 2025
EMA/CHMP/PRAC/148869/2025

Reflection paper on patient experience data



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